This record is a partial extract of the original cable. The full text of the original cable is not available.

UNCLAS ANKARA 002717

SIPDIS

DEPT FOR EB/TPP/MTA/IPE - SWILSON/JURBAN AND EUR/SE DEPT
PASS USTR FOR JCHOE-GROVES
DEPT PASS LIBRARY OF CONGRESS FOR STEPP
DEPT PASS USPTO FOR JURBAN
USDOC FOR ITA/MAC/DDEFALCO AND JBOGER

SENSITIVE

E.O. 12958: N/A
TAGS: ETRD KIPR TU USTR
SUBJECT: SPECIAL 301: HEALTH MINISTRY PLANS TO IMPROVE DATA EXCLUSIVITY REGULATION; COURT DECISIONS ON ZYPREXA

REF: (A) State 79058 (B) State 66948

(C) Ankara 2522 and previous

Summary

¶1. (SBU) The Deputy Undersecretary of the Turkish Health Ministry told us that the GOT had committed to the EC to extend data exclusivity protection to nonpatented drugs, which would address a major shortcoming in Turkey's regulatory regime. Separately, Lilly's Managing Director in Turkey informed us of positive court decisions related to the Zyprexa case, and suggested that it might be counterproductive to push the GOT on this issue at present. End Summary.

Data Exclusivity

¶2. (SBU) Meeting with Econoff and Econ Specialist on May 10, Orhan Gumrukcuoglu, the Deputy Undersecretary of Health, expressed disappointment with Turkey's Priority Watch List designation in the 2005 Special 301 review. He argued that the GOT had taken far-reaching measures to improve the environment for research-based companies, and that it plans to do more.

¶3. (SBU) Gumrukcuoglu informed us that the GOT had committed in writing to the European Commission at their joint council meeting April 26 to extend the six-year period of data exclusivity protection to non-patented molecules registered in European countries. The term of protection will begin on the date of first licensing in an EU member state. The Deputy U/S said that the EC welcomed this move, and that U.S. companies would have the most to gain from it. Gumrukcuoglu advised that GOT interagency discussions on new legislation to effect this change are ongoing and should be completed in June. Gumrukcuoglu added that the GOT would extend protection to ten years upon accession to the EU.

¶4. (SBU) While noting that the USG continues to have other intellectual property concerns in this sector, Econoff applauded the plan to offer data exclusivity to nonpatented drugs. Gumrukcuoglu responded that the GOT puts a high priority on encouraging advances in medicine, technology and IP, and that it hopes to attract investment in these areas.

Zyprexa

¶5. (SBU) In a separate meeting on May 9, Lilly Turkey's Managing Director briefed us on recent court decisions which should help the company in the Zyprexa case on potential patent infringement. One decision provided for the right of patent holders to be informed of potentially infringing copy applications. Another opens the way to making the copy manufacturer's dossier available to help establish whether an application would infringe a patent. Lilly told us that Gumrukcuoglu had asked for an in-house legal opinion on compliance with these court decisions with respect to Zyprexa.

¶6. (SBU) The Managing Director commented that Gumrukcuoglu, with whom he met just before our discussion, has been very transparent in his dealings with Lilly. The company is guardedly optimistic that these developments will either forestall final Health Ministry approval for the Abdi Ibrahim copy, or if the copy is actually approved, that Lilly would have a good chance of obtaining an injunction to stop marketing. The Managing Director thanked us for extensive USG advocacy, which he said was instrumental in raising the profile of the case at senior levels of the GOT and in preventing final approval of the copy. However, given

the strong message conveyed in our Special 301 review and other demarches and the prospect of favorable action by the Health Ministry in response to court decisions, he suggested it might be counterproductive to push the Health Ministry further on Zyprexa at this time.
Edelman